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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/186,342	11/04/98	CONKLIN	D 97-64

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JENNIFER K JOHNSON
ZYMOGENETICS INC
1201 EASTLAKE AVE EAST
SEATTLE WA 98102

EXAMINER	
LAZAR WESLEY,E	
ART UNIT	**PAPER NUMBER**
1642	6

DATE MAILED: 06/21/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/186,342	Applicant(s) Conklin
	Examiner Eliane Lazar-Wesley	Group Art Unit 1642

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-21* is/are pending in the application.

Of the above, claim(s) *11-14 and 16-21* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-10 and 15* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 5

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-10 and 15, drawn to isolated polynucleotides of SEQ ID No:1 encoding a polypeptide, classified in class 435, subclass 69.1

   II. Claims 11-14, drawn to isolated a polypeptides, classified in class 530, subclass 350.

   III. Claims 16-19, drawn to an antibody, classified in class 530, subclass 387.1.

   IV. Claims 20-21, drawn to a method of detecting an antagonist or an agonist, classified in class 435, subclass 7.1.

2. The inventions are distinct, each from the other because of the following reasons:

Groups I-III are directed to products that are patentably distinct.

Groups I and II are directed to products that are distinct both physically and functionnally, and are therefore patentably distinct. The nucleic acids molecules encoding a Polypeptide of invention I are related to the protein of invention II by virtue of encoding same. The DNA molecule has utility for the recombinant production of the protein in a host cell. Although the DNA molecule and protein are related since the DNA encodes the specifically claimed protein, they are distinct inventions because they are physically and functionnally distinct chemical entities, and the protein product can be made by another and materially different process, such by synthetic peptides synthesis or

purification from the natural source. Further, the DNA may be used for processes other than the production of the protein, such as nucleic acid hybridization assay.

The proteins of invention II are related to the antibodies of invention III by virtue of being cognate antigens, which may be used for the production of the antibodies. Although the protein and antibody are related due to the necessary stearic complementarity of the two, they are distinct inventions because they are physically and functionnally distinct chemical entities, and because the proteins can be used in other and materially different processes from the use for production of the antibody, such as in pharmaceutical compositions, or in a diagnostic assay or for therapeutic purposes.

Inventions I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case , the nucleic acids of Inventions I can be used as an hybridization probe..

Inventions II-III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, and because the searches

required for each of the groups are different, restriction for examination purposes as indicated is proper.

4. During a telephone conversation with Jennifer Johnson on June 01, 2000, a provisional election was made with traverse to prosecute the invention of Group I, claims 1-10 and 15. Affirmation of this election must be made by applicant in replying to this Office action. Claims 11-14 and 16-21 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112, second paragraph

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 5-9 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 5 and 7 recite a z219**a** polypeptide, while claim 15 recites a z219**c** polypeptide. However, from the specification, it seems that Applicants mean all along a z219**c** polypeptide. For the purpose of compact prosecution, the Examiner has analyzed the claims as addressed to z219c . Applicant is requested to amend the claims.

Claim 5 lacks antecedent basis for "the z219a polypeptide" in claim 4.

Claim 6 is confusing, as it is not clear what structure is claimed, and what the motifs are. Applicants discloses, page 14, structural elements of the claimed polynucleotide. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Claim 7 recites a z219a polypeptide, but it is not clear what the final limitations of the polypeptide are.

Claim Rejections - 35 USC § 101 and 35 USC § 112, first paragraph

8. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 1-9 and 15 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific asserted utility or a well established utility.

The nucleic acid encoding z219c has been obtained by scanning of translated database and confirmation of EST sequence (page 84, example 1).

The specification sets forth various utilities for the claimed nucleic acid and encoded protein; however, none are specific to the nucleic acid claimed. Applicants disclose that, by performing Northern blot analysis, (Example 2, page 85 and page 86), the nucleic acid shows a wide tissue distribution.for z219c (trachea, stomach,colon, pancreas, prostate, small intestine, salivary gland, kidney, fetal kidney, fetal liver, fetal spleen, fetal thymus, and fetal lung). Applicants also show a chromosome localization for z219c (Example 3). While applicants recite that z219c expression has been detected by Northern analysis at various levels in numerous tissues, applicants do not teach where z219c is not expressed. The fact that z219c is expressed in some selected tissues does not exclude *per se* thatz219c is not expressed also in other tissues. One of skill in the art must know where the nucleic acid is not expressed in order for it to be useful , for example in tissue identification.

The assertions of utility are found to be non-specific, as they could apply equally to any nucleic acid or encoded protein obtained from nature, and thus do not fulfill the requirements of 35 U.S.C. 101.

11. Claims 1-9 and 15 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

12. Claims 1, 3-10 and 15 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 1, 4, 7 and 10 recite a polynucleotide encoding a protein at least 90% identical to amino acid sequence of SEQ ID No:2 from amino acid 23 to 223 (claims 1, 4 and 7), or a DNA encoding a polypeptide at least 90% identical to SEQ ID No:2 from position 1-21 (claim 10). As no specific function is provided for the z219c polypeptide, it is unpredictable which amino acids and nucleotides could be modified in order to maintain the unknown function of the protein.In view of the state of the art, of the lack of guidance about which amino acids are essential for the function, and which function, of z219c, and of the lack of working examples, it would constitute undue experimentation to make and use the invention of claims 1, 2-9 and 15. While one of skill in the art would know how to use the predicted signal sequence at position 1-21 of SEQ ID No:2 (claim 10), one of skill in the art would not know how to make the claimed invention, and how to use a polypeptide 90% identical to the signal peptide that is not functional.

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Billing-Medel et al, WO 98441333, 08 October 1998, cited by applicants, teaches a protein that is 100% identical to the instant polypeptide of SEQ ID No:2 over its entire length (position 1-223). The date of publication is later than the filing date of the provisional application 60/066,157, filed November 19, 1997.

Yu et al., US Patent 5,733,748, 31 March 1998, teaches a protein that is 100% identical at position 1-135 to the instant SEQ ID No:2 at position 89-223.

Yu et al, WO 9639149, 12 December 1996, cited by applicants, teaches a protein that is 100% identical at position 1-135 to the instant SEQ ID No:2 at position 89-223.

Hillier et al., Genbank Accession Number AA622758, 21 October 1997, cited by applicants, teaches an EST that is 98% identical at position 8-564 to the complement of the instant SEQ ID No:1 at position 663-1220.

14. No claim is allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eliane Lazar-Wesley, PhD, whose telephone number is (703) 305 4059. The examiner can normally be reached on Monday-Friday from 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995.

Official papers filed by fax should be directed to (703) 308 4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

ELW
June 19, 2000
ELW

Lorraine Spector

LORRAINE SPECTOR
PRIMARY EXAMINER